THE HONORABLE MARSHA J. PECHMAN

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

KENNETH McGUIRE, On Behalf of Himself and All Others Similarly Situated,

Plaintiffs,

v.

DENDREON CORPORATION, et al.,

Defendants.

CASE NO.: C07-800-MJP

Consolidated Class Action

DECLARATION OF DAVID URDAL IN SUPPORT OF DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT IN *MCGUIRE V. DENDREON* AND *MOUNTANOS V. DENDREON*

Note on Motion Calendar:
July 30, 2010

ORAL ARGUMENT REQUESTED

This document relates to:

All Actions.

WILLIAM MOUNTANOS, PETER MOUNTANOS, JAMES RYE, and TYRONE REMINGA,

Plaintiffs,

v.

DENDREON CORPORATION, a Delaware Corporation, MITCHELL GOLD, and DAVID URDAL,

Defendants.

CASE NO.: C09-426-MJP

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I, David Urdal, declare:

1. I am the Chief Scientific Officer, and a Senior Vice President, of Dendreon Corporation ("Dendreon" or "Company"). I make this declaration in support of Defendants' Motion for Partial Summary Judgment in *McGuire v. Dendreon* and *Mountanos v. Dendreon*, filed concurrently herewith. I am familiar with the facts set forth herein and could and would testify thereto if necessary.

2. When Dendreon's Biologics License Application ("BLA") for Provenge (sipuleucel-T) was pending in 2006 and 2007, the Company's primary objective was to gain Food and Drug Administration ("FDA") licensure of this product. Our strategy was to direct our resources toward those efforts necessary to gain FDA approval, and then, following approval, to focus on a phased rollout for the commercial production and sale of Provenge. As Chief Scientific Officer for Dendreon, my focus during this time period was on gaining FDA approval for Provenge, in line with the Company's primary objective.

3. Dendreon submitted the Provenge BLA in 2006 after having had an encouraging meeting with the FDA in 2005, at which the Company presented evidence that, despite the fact that the two key clinical efficacy trials for Provenge under way at the time had missed their primary endpoint of delaying time-to-disease progression, the studies had shown provocative evidence that treatment with Provenge extended the lives of men with late-stage prostate cancer. The FDA expressed their openness to reviewing these clinical data as the basis of a BLA. I knew that the FDA did not normally license products under these conditions, but was hopeful that the FDA would nonetheless approve Provenge, because it was designed to serve patients with terminal disease who had few other treatment options. In this context, gaining approval for Provenge would have been a tremendous achievement for Dendreon, and would have allowed us to make available to patients a revolutionary new treatment for cancer – without waiting for the conclusion of an additional clinical trial ("D9902B" or "IMPACT") which, although already under way at the time the BLA was being considered, might take years to produce conclusive results.

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4. I was encouraged by the recommendation made to the FDA by the Cellular, Tissue and Gene Therapies Advisory Committee ("Advisory Committee") on March 29, 2007, which voted 17-0 that Provenge was reasonably safe, and 13-4 that there was substantial evidence of its efficacy. Because I knew that the FDA generally follows the recommendations made by its advisory committees, I believed this positive vote increased the likelihood that the FDA would approve Provenge in 2007.

5. Despite the positive vote from the Advisory Committee, however, it was obvious that concerns over the clinical efficacy data drove the FDA's subsequent decision to send us a Complete Response Letter on May 8, 2007. Senior management at Dendreon understood that efficacy concerns were the basis for the Complete Response Letter, and that the remaining items listed in the letter could have been resolved before the FDA's target action date of May 15, 2007 – if the FDA had believed our clinical trial data was sufficient to support approval. This belief was confirmed by our discussions with FDA representatives, who told us in the time period following the Complete Response Letter that their approval decision was driven by concerns over the sufficiency of Dendreon's clinical trials, and that absent these concerns, the items listed in the Complete Response Letter relating to CMC issues (including the item mentioning the facility inspection), could have been resolved in a short period of time.

6. As Dendreon's Chief Scientific Officer in 2007, I was the senior executive in charge of supervising our manufacturing operations. I knew that in order to host a successful PLI, Dendreon needed to conduct the inspection in an organized, responsive, and professional manner. I was proud of how the Dendreon team performed during the 2007 PLI. I personally observed many positive interactions between Dendreon and the FDA during the inspection, and I was pleased by the reports made to me by key supervisors and staff members. Although there are ups and downs during every FDA inspection, I thought Dendreon staff members were professional, responsive to FDA concerns and requests, and behaved in a way that was a positive reflection on the organization as a whole. During the final closeout meeting for the inspection, FDA inspectors confirmed this impression with positive remarks about Dendreon's performance

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in hosting the inspection. I left this closeout meeting with a positive feeling about the inspection, as well as a positive feeling about how the FDA was reacting to our BLA as a whole.

7. Part of hosting a successful inspection is the ability to respond to FDA concerns as they arise – so that these concerns are either not ultimately reflected in the Form 483; the FDA inspectors understand the issues better before drafting their Form 483 observations; or the Company can get a head start in addressing these concerns before the inspection ends. I believe Dendreon did this effectively. For example, when there was misunderstanding about how Dendreon performed shop floor management activities, we organized a presentation to the FDA to clarify that these duties were currently performed by our manufacturing supervisor, and that an additional position would be filled as our manufacturing levels increased. *See* Ex. 20 (Dendreon's debriefing notes from the PLI, reflecting the discussion of shop floor activities). Similarly, after the FDA expressed concerns about the layout of our Quality Control Laboratory, and whether the laboratory had sufficient redundant equipment, Dendreon staff acted immediately to begin to address these concerns. *See* Ex. 21 (email reflecting action taken in anticipation of possible Form 483 observation on these topics).

8. I believed that the Form 483 that Dendreon received at the conclusion of the 2007 PLI reflected the fact that it had been a successful inspection. *See* Ex. 22 (2007 Form 483). Based on my knowledge and experience, and the experience and expertise of my key staff members, I fully expected that we would receive a Form 483 at the conclusion of the inspection, even if the inspection went very well. I was pleased that the observations on the Form 483 were limited in number, and that they were issues that I believed we could address in a timely and effective way, so that they would not impede approval of the Provenge BLA in 2007. Most importantly, I did not believe that any of the Form 483 observations were "showstoppers" that presented an obstacle to our primary goal of receiving FDA approval for Provenge. Specifically, I believed that none of the observations questioned the quality of the product being manufactured or the adequacy of our basic manufacturing system, but instead focused on issues that would be relatively straightforward to address – such as manufacturing logistics, the need to submit

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additional information or data to the FDA, and the need to clarify for the FDA some aspects of our manufacturing process.

9. As a senior Dendreon executive, I rely heavily on my leadership team to keep me informed of important events and to supervise the Dendreon team in the preparation for, and the conduct of, events such as the PLI. I also rely upon the expertise and experience of this leadership team in helping me set expectations for events such as the PLI, and in evaluating their success. In 2007, members of this key leadership team included, among others, Elizabeth Smith, Dendreon's Vice President of Regulatory Affairs; Mary Coon, Vice President of Quality; Andrew Scherer, Vice President of Manufacturing; and Ernie Bognar, Plant Manager for the New Jersey manufacturing facility. The message I received from my leadership team was that the 2007 PLI was a success, that we had hosted a good inspection, and that Dendreon could address all of the Form 483 observations in a timely and effective way.

10. In turn, as the senior Dendreon executive with supervision over manufacturing and quality issues, it was my responsibility to keep Dendreon CEO Mitchell Gold updated on these activities. During the course of the PLI, I had regular communications with Dr. Gold by email or telephone to communicate with him about the progress of the inspection, and I also spoke with him following the conclusion of the inspection, and during the course of our communications with the FDA about inspectional issues. At all these points in time, I communicated to Dr. Gold my positive impressions of the inspection, and my belief that Dendreon could address all the Form 483 observations in a timely and effective way, so that they would not present an obstacle for the approval for Provenge.

11. Because I understood the importance of a timely and thorough response to the Form 483 observations, I encouraged my staff to mobilize quickly after the PLI to evaluate the observations and formulate an action plan in response to each, and to submit responses to the FDA as promptly as possible. My team submitted comprehensive responses to the FDA within 10 business days after the PLI, and the content of these responses reinforced my impression that all of the Form 483 observations could be addressed in a timely and effective way. *See* Ex. 26

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(Dendreon's March 2, 2007 responses to the Form 483 observations). I was impressed by our performance in assembling these responses, and thought that they presented an action plan to the FDA that would be sufficient to resolve each observation in advance of the May 2007 PDUFA date.

12. Following the conclusion of the 2007 PLI, and the receipt of the 2007 Form 483, Dendreon hosted a dinner for the team that worked so hard to make the inspection a success. During this dinner, I thanked the team for a job well done. The mood at the dinner was celebratory, as Dendreon staff expressed a sense of relief at the successful culmination of months of hard work and preparation for the PLI.

13. I gave a report to the Dendreon Board of Directors on March 2, 2007 regarding the PLI, during which I communicated my positive feelings about how the inspection had gone, as well as my sense of optimism that we would be able to address all of the Form 483 observations in a timely and effective manner. Neither I nor other members of the Board expressed concern during this meeting about whether the PLI would be an obstacle to approval. The minutes from this meeting paraphrase my remarks. *See* Ex. 34 (minutes from March 2, 2007 board meeting). Although these minutes are consistent with my memory that I believed three of the Form 483 observations to be more important than the remaining six observations, the characterization of these observations does not reflect the full context of my report. For example, I knew that any concerns over resource and staffing issues could be addressed following approval, when we ramped up our manufacturing capacity, and hired additional staff. In addition, I was aware that the chain of identity issues mentioned by the FDA related specifically to the samples in the Quality Control laboratory, and that these concerns had been addressed in Dendreon's responses to the Form 483.

14. The phone log from the due diligence call with Pfizer on April 12, 2007 reflects only a cursory recap of my remarks. *See* Ex. 35. During this call, I did not classify any of the Form 483 observations as potential impediments to the approval of Provenge. If I did use the word "major," which I do not recall doing, it was in describing the relative importance of the

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Form 483 observations as compared to one another, not to communicate that I thought any of them was "major" in a broader context.

15. Following the PLI, and until shortly after the Advisory Committee meeting, Dendreon had regular, productive interactions with the FDA. I believed that the FDA's request after the PLI to schedule weekly conference calls with Dendreon reflected its desire to work closely with us to resolve any remaining issues prior to the May PDUFA date. My staff and I agreed that these communications with the FDA represented continued progress toward the goal of FDA approval by the May 2007 PDUFA date.

16. I participated in a March 23, 2007, conference call with FDA representatives in which we discussed some final issues in preparation for the upcoming Advisory Committee meeting. During this call, FDA representatives told us that they also wanted to raise one issue in regard to our March 2, 2007 responses to the Form 483 observations. Although they believed that our proposals to respond to eight of the nine observations would necessitate only minor amendments to the BLA (and thus no delay in the approval process), they told us that they thought our proposal to submit additional data in response to Observation 1 might require a major amendment that could delay the May 15, 2007 PDUFA date. In response, Dendreon expressed our desire to keep the May 15, 2007 PDUFA date, and proposed a path to address Observation 1 so that it would not push back this date. Our proposal was for initial FDA approval with limitations on manufacturing based on the FDA's communications about what it believed to be supported by the existing data, with a plan to immediately submit additional data following approval so these restrictions would be lifted. The FDA expressed its openness to this proposal, but said that it was not prepared to immediately discuss the details of our plan, and would do so in a conference call to be scheduled after the Advisory Committee meeting.

17. I left the March 23, 2007 conference call with a feeling of optimism about Dendreon's progress toward FDA approval, because FDA representatives had given positive feedback regarding our responses to eight of the nine Form 483 observations, and expressed a desire to work with us toward resolving the remaining observation so that it did not delay the

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PDUFA date. It appeared that the FDA raised the issue about the Form 483 observations during this conference call – despite its focus on the upcoming Advisory Committee meeting – because it wanted to expedite resolution of this issue, and allow sufficient time to work with us to resolve the concern in advance of the PDUFA date. The FDA did not raise any concerns during this conference call that indicated that the Form 483 observations would prevent FDA approval of Provenge, or that they could not be resolved in a mutually acceptable way before the PDUFA date. To the contrary, the March 23, 2007 conference call gave me a sense of increased comfort that we were on a path to resolve all of the Form 483 observations before the PDUFA date.

18. During Dendreon's investor conference call immediately following the March 29, 2007 FDA Advisory Committee meeting, and the Advisory Committee's positive votes on the efficacy and safety of Provenge, I answered a question about the PLI by expressing my honest opinion. *See* Ex. 1 at 6 (transcript of March 29, 2007 conference call). After Dr. Gold said that the FDA had conducted an inspection of the New Jersey facility, I answered follow-up questions about that inspection, since as Dendreon's Chief Scientific Officer, it was customary for me to respond to such inquiries. The questions that were simultaneously posed were whether or not our manufacturing facility had "passed the muster," or if we could give any 'insights" about the PLI. I responded honestly with my insight that Dendreon had "hosted a good inspection, I think" and also conveyed that our discussions with the FDA about these activities were ongoing. My answer conveyed my sincere opinion about the PLI, as well as my impression of the current status of inspectional issues: I believed that we had "hosted a good inspection" and that the results of that inspection indicated that it had been successful, but I was aware that these activities were still being discussed with the FDA, and that according to FDA guidelines, there would be no official resolution to these issues until the FDA approved our BLA.

19. In attempting to formulate a fair answer to the questions posed regarding the PLI, I did not make a conscious decision not to use the words "Form 483." I do not believe that the use of those words was necessary to give my honest insight into the PLI, or that the existence of the Form 483 was in any way in conflict with my opinion that we had "hosted a good

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inspection." The Form 483 reflects observations made by one or more of the FDA inspectors who are on site during the PLI. As such, these observations were the first step in an ongoing discussion with the FDA about inspectional issues, and it is not customary for Dendreon – and I do not believe that it is customary in the industry as a whole – to disclose the specific details of these discussions as they take place. By disclosing that we were having these ongoing conversations with the FDA to finish the review of the CMC section, however, I believe that I conveyed an accurate overall impression about the current state of those activities.

20. Following Dendreon's receipt of the Complete Response Letter on May 8, 2007, we released a press release on May 9, 2007 disclosing this letter. *See* Ex. 39 (May 9, 2007 press release). This press release indicated that we had received a Complete Response Letter and that the FDA had requested additional data related to the efficacy of Provenge. It also mentioned that the FDA had requested additional information regarding the Chemistry, Manufacturing, and Controls ("CMC") section of the BLA, which Dendreon believed it could supply in a timely manner.

21. In addition to Item 1, which refers to inspectional issues, the Complete Response Letter contains six other numbered items that relate to the CMC section of the BLA. None of these items relate to observations on the Form 483, and the FDA did not tie them to any issues otherwise raised during the 2007 PLI. While review of the CMC section of the BLA includes an inspection of manufacturing facilities, it also includes review of a number of unrelated issues – such as the items mentioned in the Complete Response Letter related to shipping validation, data on the stability of the apheresis product, manufacturing comparability data, and analytical testing methods. Therefore, Dendreon's reference in its May 9, 2007 press release to the FDA's requests for more information about the CMC section of the BLA is properly understood as a reference to all seven items of the Complete Response Letter that related to the CMC section, not as a reference to the single item relating to inspectional issues.

22. In my view, the key portion of the Complete Response Letter was the FDA's comment that the clinical efficacy data submitted by Dendreon was not sufficient to support

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licensure. We sought clarification from the FDA in the weeks following the Complete Response Letter about what additional data it would require in order to support licensure of Provenge, but the language of the Complete Response Letter raised the possibility that the FDA would not approve Provenge until we had received final results from our IMPACT trial. Since this trial measured the survival benefits of Provenge, it could not be concluded until a specified number of deaths had occurred among trial participants, which meant that final data from the trial might not be available until 2010. The parameters of the IMPACT trial, and the estimated date for its completion, were discussed during the public Advisory Committee meeting on March 29, 2007, as well as during Dendreon's March 29, 2007 and May 10, 2007 conference calls. *See* Ex. 2 at 84-85 (Advisory Committee transcript); Ex. 1 at 15 (discussion during March 29, 2007 conference call); Ex. 36 at 11 (discussion during May 10, 2007 conference call).

23. Ultimately, the IMPACT trial did need to be completed before the FDA was satisfied that there was sufficient clinical data to support the efficacy of Provenge. Dendreon received the results from this trial in spring 2009, submitted them to the FDA in November 2009, and received approval for Provenge on the strength of the data from this trial on April 29, 2010.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge. Executed in Seattle, WA, on June 21, 2010.

David Urdal by email permission; signed copy to follow

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2010, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record who receive CM/ECF notification.

Dated: June 21, 2010

s/ Barry M. Kaplan
Barry M. Kaplan, WSBA#8661

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